IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

THE UNITED STATES OF AMERICA *ex rel.* [UNDER SEAL],

Plaintiffs,

v.

[UNDER SEAL],

Defendant.

UNDER SEAL

Qui tam action filed in camera and under seal in accordance with 31 U.S.C. § 3730(b)(2)

Civil Action No. _____

COMPLAINT

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

THE UNITED STATES OF AMERICA *ex rel.*
JAMES WATKINS, M.D.,
ABINO ORTEGA, R.N., and
ROBERT SMITH, D.P.M., M.Sc., R.Ph.,

Plaintiffs,

v.

CHS MIDDLE EAST, LLC,

Defendant.

UNDER SEAL

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COMPLAINT

1. Plaintiff relators James Watkins, M.D., Abino Ortega, R.N., and Robert Smith, D.P.M., M.Sc., R.Ph. (collectively, "Relators") bring this action on behalf of the United States against CHS Middle East, LLC ("CHS") for violations of the False Claims Act, 31 U.S.C. §§ 3729 *et seq*. (the "FCA") to recover all damages, civil penalties and other recoveries provided for under the statute.

I. INTRODUCTION

2. Although the war in Iraq ended in 2011, the United States remains broadly engaged with Iraq on diplomatic, political, economic, and security issues. Consequently, a significant number of U.S. troops have continued operating in Iraq to advise and assist in the campaign against ISIS, to help train Iraqi soldiers, and to provide security at the U.S. embassy in Baghdad and other U.S. installations. The U.S. embassy in Baghdad, which is the largest in the world, houses more than 2,000 U.S. Government civilians, military, and contractors who are carrying out the United States' diplomatic mission in Iraq. The U.S. also has consulates with large staff, in multiple cities in Iraq, including Basrah.

3. To ensure that American troops, coalition forces, government civilian employees and contractors, and other men and women assisting the United States' mission in Iraq receive U.S.-quality medical and trauma care, the U.S. Department of State ("DoS") has been paying CHS significant sums since 2011 to operate medical facilities at different sites in Iraq, including hospitals at the U.S. embassy in Baghdad and the U.S. consulate in Basrah. The official name of this multi-year contract (five years with options for additional years) is the Medical Services Support Iraq contract (contract no. SAQMMA-11-D-0073). To satisfy the quality of care standards required under the contract, CHS must staff essential hospital functions, including surgery, pharmacy, and radiology, in accordance with the staffing levels stated in the contract.

4. As explained more fully below, throughout the life of the contract, CHS has continuously disregarded the quality of care and staffing requirements for the surgical, pharmacy, and radiology functions at the hospitals at the U.S. embassy in Baghdad and the U.S. consulate in Basrah. CHS systematically cut corners and reduced its staff to skeleton crew levels at the hospitals in order to save costs. It thereby knowingly defrauded the U.S. government.

5. These staffing deficiencies resulted in untrained and nonqualified individuals performing highly-specialized essential medical services. For instance, dentists and even lay persons served as surgical assistants; pharmacy technicians and nurse anesthetists served as pharmacists; and radiology technicians lacking proper training performed computed tomography (CT) scans and were responsible for maintaining the CT equipment. Given the critical role that CHS plays as the single largest provider of medical care to government contractors, DoS civilian employees and third party nationals supporting the U.S.-led mission in Iraq, these failures have jeopardized not only the health and safety of the individuals CHS was given responsibility for but the Unites States' mission as a whole.

6. If DoS knew that a significant portion of the surgical, pharmacy, and radiology services that CHS has been providing at the Iraq hospitals has been performed by untrained and unqualified individuals and that the quality of the services has been far below U.S. standards, it would not have paid CHS for the services. Nor would the U.S. government tolerate American servicemen and servicewomen, DoS personnel, government contractors, and members of allies' militaries receiving such grossly substandard care and being subjected to increased risk of significant injury and bodily harm.

II. JURISDICTION AND VENUE

7. Jurisdiction is founded upon the FCA, 31 U.S.C. §§ 3729 *et seq.*, specifically 31 U.S.C. §§ 3732(a) & (b) and also 28 U.S.C. §§ 1331 & 1345. This Court has personal jurisdiction over CHS because it transacts business in this District.

8. Venue in this District is appropriate under 28 U.S.C. § 1391(b) & (c) and 31 U.S.C. §3732(a) in that the defendant may be found, resides, and/or transacts business in this District.

9. The facts and circumstances of CHS's violations of the FCA have not been publicly disclosed in a criminal, civil, or administrative hearing in which the Government or its agent is a party, nor in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation, or in the news media.

10. Relators are the original sources of the information upon which this Complaint is based, as that phrase is used in the FCA, and they voluntarily disclosed the information and allegations in this Complaint to the United States prior to filing the Complaint with the Court.

III. THE PARTIES

11. The real party in interest in this case is the United States of America, which contracted with CHS through DoS.

12. Relator James Watkins, M.D. ("Dr. Watkins") is a general surgeon who contracted with CHS to provide surgical services under the terms of a Foreign Service Agreement ("FSA") from October 2015 to October 2016 at the large diplomatic support hospital at the Baghdad Diplomatic Support Center. Dr. Watkins received his medical degree from the Columbia College of Physicians and Surgeons in 1992 and performed his surgical residency at Beth Israel Hospital in Boston. Additionally, Dr. Watkins was a Fellow in Trauma and Surgical

Critical Care at the R. Adams Cowley Shock Trauma Center in Baltimore and for years was part of the trauma faculty at Harvard Medical School. Prior to working with CHS, Dr. Watkins was the chief of surgery at the Grand Junction Veterans Affairs Medical Center in Grand Junction, Colorado. He is, and was at all relevant times, Board Certified as a general surgeon with the certificate of added qualifications in surgical critical care. Dr. Watkins is currently working as a contract trauma surgeon at Tufts Medical Center in Boston.

13. Relator Abino Ortega, R.N. ("Nurse Ortega") is an operating room nurse who worked as a contractor for CHS under multiple FSAs from 2012 until June 2017. While he worked with CHS, Nurse Ortega worked in the operating room at the large diplomatic support hospital at the Baghdad Diplomatic Support Center. Nurse Ortega received a Bachelor of Science in nursing from the University of South Carolina in 1980. Prior to working with CHS, he was a remote duty nurse in Iraq and the Director of Nursing for the Kingdom of Saudi Arabia.

14. Relator Robert Smith, D.P.M., M. Sc., R.Ph. ("Dr. Smith") is a pharmacist licensed in Florida as well as a podiatrist who worked as a contract pharmacist for CHS at different times between 2014 and 2016. He worked with CHS in 2015 and 2016 as a pharmacist for the large diplomatic support hospital at the Baghdad Diplomatic Support Center. He also worked with CHS as a pharmacist in Balad, Iraq, from 2014 to 2015 under a different DoS contract. Dr. Smith earned a Bachelor of Science in pharmacy from the University of Florida in 1983. He also received a Doctor of Podiatric Medicine from the University of Osteopathic Medicine and Health Sciences in 1999. And in 2006, Dr. Smith earned a Master of Science in Wound Care and Tissue Repair from the University of Wales. Prior to his contracts with CHS, Dr. Smith was employed as a contract clinical pharmacist at Joint Base Elmendorf-Richardson

Air Force Base in Anchorage, Alaska, from 2013 to 2014 and as a pharmacist at Florida Hospital-Flagler and Florida Hospital-Memorial Medical Center from 2001 to 2013.

15. Defendant CHS Middle East, LLC ("CHS") is a Florida limited liability company that provides medical and support services in the Middle East under contracts with DoS. CHS maintains its principal executive offices in Cape Canaveral, Florida, at the same location where its parent, Comprehensive Health Services, Inc. ("CHSI"), maintains its headquarters. CHSI is a privately-owned corporation that provides medical and support services under contract to governments and other entities throughout the United States and the world.

IV. LEGAL BACKGROUND

16. The FCA provides, in relevant part, that any person who:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> is liable to the United States Government for [statutory damages and such penalties as are allowed by law].

(31 U.S.C. §§ 3729(a)(1)(A) & (B)).

17. Section 3729(a)(1) of the FCA provides that a person is liable to the United States Government for three times the amount of damages that the Government sustains because of the act of that person, plus a civil penalty of $5,000 to $10,000 per violation. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), 64 Fed. Reg. 47099, 47103 (1999), and 28 C.F.R. § 85.3 (2015), the FCA's civil penalties were adjusted to $5,500 to $11,000 for violations occurring on or after October 23, 1996. In accordance with the Federal Civil Penalties Inflation Adjustment Act of 2015, the FCA civil penalty amounts were again adjusted, this time to

$10,957 to $21,916 per violation for violations occurring after November 2, 2015. (*See* 28 C.F.R. §§ 85.3 & 85.5 (2016); 81 Fed. Reg. 42491, 42500 (2016)).

18. The terms "knowing" and "knowingly" are defined at 31 U.S.C. § 3729(b)(1)(A) to mean that a person with respect to information:

(1) "has actual knowledge of the information";

(2) "acts in deliberate ignorance of the truth or falsity of the information"; or

(3) "acts in reckless disregard of the truth or falsity of the information."

The plaintiff is not required to prove specific intent to defraud. (*See* 31 U.S.C. § 3729(b)(1)(B)).

V. FACTUAL ALLEGATIONS

A. CHS's Multi-Year Contract To Provide U.S.-Quality Medical Services In Iraq For American Servicemen And Servicewomen, Government Civilian Employees And Contractors, Coalition Forces, And Other Persons Assisting The U.S. Mission

19. In May 2011, CHS entered into the multi-year Contract (contract number SAQMMA11D0073) with DoS in which CHS agreed to establish and operate multiple medical facilities located at different sites in Iraq on a 24-hour, seven-days-per-week, 365-days-per-year basis (the "Contract").[1] The Contract is an indefinite delivery, indefinite quantity contract that has a value of up to $1 billion. (*See* Contract at 5).[2]

20. DoS is implementing the Contract through several task orders. The type, complexity and urgency of a particular task order determines the manner in which CHS bills – and DoS pays – for the services that CHS provides (*i.e.*, fixed-price, cost-reimbursement, labor-hour, or time-and-materials basis). (*See* Contract at 3). Task Order No. SAQMMA-15-F-1220 (the "Task Order") governs the medical services CHS provided under the Contract from May 19,

[1] The relevant pages of the Contract are appended hereto as Exhibit A.

[2] DoS has the ability to add or remove medical facilities from the Contract. Although twelve facilities are identified in the Contract, the Task Order only references five locations.

2015 through May 18, 2017 and therefore is one of the operative task orders for the grossly substandard services upon which the alleged FCA violations are based.[3] [4]

21. ***Medical Facilities***: Under the Task Order, DoS contracted with CHS to operate a large diplomatic support hospital at the Baghdad Diplomatic Support Center ("BDSC Hospital"), which provides hospital services to a population of approximately 1,800, and a small diplomatic support hospital at the U.S. Consulate in Basrah ("Basrah Hospital"), which provides hospital services to a population of approximately 800. In addition, DoS contracted with CHS to operate three smaller health units located at the Baghdad Embassy Compound ("BEC Health Unit"), Condor ("Condor Health Unit"), and Erbil/Ankawa ("Erbil Health Unit").

22. ***Medical Services Provided***: Under the Contract and Task Order, CHS is contractually required to provide U.S. troops, government civilian employees and contractors, coalition forces, and other men and women assisting the U.S. mission specified health services at the two hospitals and three health units. Importantly, the services are required to be provided in accordance with U.S. or equivalent medical standards. (*See* Task Order at 38).

(a) *At BDSC Hospital,* CHS is required to provide, among other things:

- On-site primary, urgent and initial emergency care for general medical, surgical, orthopedic, gynecologic, and mental health conditions; triage, stabilize and evacuate patients to the next level of medical care….
- Staffing to manage two surgical patients and multiple injured or ill patients.
- Two surgical tables with accompanying anesthesia and supplies.
- Post-operative/intensive care capabilities for up to six patients to be stabilized until medically evacuated.

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[3] The relevant pages of the Task Order are appended hereto as Exhibit B.

[4] Relators do not have access to the relevant task orders that DoS issued before and after Task Order No. SAQMA-15-F-1220.

- Medical supplies and equipment, to include medical emergency equipment, basic formulary and vaccines, laboratory equipment and supplies at a level appropriate for the required services in this task order.

- A system to receive, store and provide medical prescriptions to Chief of Mission personnel who are eligible and have agreed to the conditions of this service.

- Computerized Tomography (CT) scanner with the capability to conduct non-contrast, contrast (oral and IV), and the ability to do PA-grams (ideally with venous run-off).

(Task Order at 26-27).

(b) At *Basrah Hospital*, CHS is required to provide, among other things:

- On-site primary, urgent and initial emergency care for general medical, surgical, orthopedic, gynecologic, and mental health conditions; triage, stabilize and evacuate patients to the next level of medical care….

- Staffing to manage a single patient with the required operating room technicians, nurses, anesthetists and the possibility of multiple injured or ill patients.

- Staffing to man one operating room table with anesthesia and supplies.

- Post-operative/intensive care capabilities for up to four patients to be stabilized until medically evacuated.

- Medical supplies and equipment, to include medical emergency equipment, basic formulary and vaccines, laboratory equipment and supplies at a level appropriate for the required services in this task order.

- Computerized Tomography (CT) scanner with the capability to conduct non-contrast, contrast (oral and IV), and the ability to do PA-grams (ideally with venous run-off).

(Task Order at 25-26).

23. ***Staffing Levels at Each Medical Facility*:** The Task Order sets forth the following requirements for "continuous and uninterrupted" staffing of the operating rooms, pharmacies, and radiology centers at BDSC Hospital and Basrah Hospital:

Position	BDSC Hospital	Basrah Hospital
General Surgeon(s)	2.75[5]	1.25
Operating Room Nurse(s)	1.75	1.25
Operating Room Technician(s)	1.75	1.25
Registered Nurses	2.00	2.00
Registered Nurse - Lead	1.00	1.00
Nurse Anesthetist(s)	2.75	1.25
Pharmacist	1.00	-
Pharmacy Technician(s)	1.75	1.25
Radiology Technician(s)	2.75	1.25

(*See* Task Order at Attachment D: Approved Staffing Plan).[6]

24. ***Medical Personnel***: The Task Order and Contract require that all medical personnel satisfy the following requirements:

- "All health care providers are licensed to U.S. or equivalent standards and physicians shall be qualified by U.S. or equivalent specialty boards."
- "All health care providers remain licensed, certified and credentialed throughout the performance of this task order."
- "All Contractor Personnel are qualified, and/or have the proper training, credentials, certifications, and licenses in accordance with the contract."

(Task Order at 40, 44-45; accord Contract at 10-11).

25. ***CHS's Oversight of the Contract***: Program Manager Marybeth Morrell, Deputy Program Manager Nelson Aguilar, and Chief Medical Officer Michael Wynn have been responsible for CHS's implementation and compliance with the Contract and Task Order and, accordingly, the operation of the medical facilities in Iraq, including BDSC Hospital and Basrah Hospital.[7]

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[5] Under the Contract and Task Order, certain practitioners/technicians will spend 75% of the year working at BDSC Hospital and 25% of the year working at Basrah Hospital.

[6] Although the Task Order covers 2015, similar staffing requirements were required for these facilities in the other years of the Contract.

[7] As DoS's Office of Inspector General recognized in a December 2014 report, there was little government oversight of CHS in the second half of 2014 because the U.S. Government had

B. CHS's Disregard Of The Contract's Requirements And For The Health And Safety Of The Men And Women Serving The U.S. Mission In Iraq

26. Since 2011 and continuing through the present, CHS has knowingly and consistently failed to comply with the most fundamental requirements of the Contract and has thereby placed military and civilian government personnel in harm's way by failing to provide adequate medical staffing, filling critical highly-skilled positions such as lead surgical assistants, pharmacists, and radiology technicians with wholly untrained and unqualified individuals, and failing to properly maintain equipment used to perform CT scans, all in flagrant violation of the Contract and the task orders issued thereunder.

27. In obtaining payment for these services, CHS knowingly misrepresented its compliance with these fundamental requirements of the Contract and task orders and thus presented or caused to be presented false or fraudulent claims for payment under the FCA. If CHS had disclosed to DoS that it was using untrained and unqualified individuals to perform highly-specialized medical services in the place of surgeons, operating room nurses, pharmacists, and radiology technicians specializing in CT scans, DoS would have refused payment (and demanded compliance or even rescinded the Contract). DoS would not have allowed the patients to be subjected to risk of harm or injury from medical services that are far below U.S. hospital and pharmacy standards.

28. Each of the Relators witnessed CHS's violations firsthand. Dr. Watkins performed surgeries at BDSC Hospital from 2015 to 2016; Nurse Ortega was an operating room

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evacuated all non-essential personnel from Iraq during that period. Indeed, the contracting officer's representative as well as the assistant contracting officer's representative who were specifically responsible for the Contract were among those who were evacuated and thus DoS relied upon CHS to be honest in its compliance with the Contract's requirements. (*See* Dec. 23, 2014 Management Assistance Report - Concerns With the Oversight of Medical Support Service Iraq Contract No. SAQMMA11D0073 (AUD-MERO-15-20) at 3-4).

nurse at BDSC Hospital from 2012 to June 2017; and Dr. Smith was a pharmacist at BDSC Hospital in 2015 and 2016.

1. CHS disregarded required staffing levels for surgeries and utilized unqualified personnel to provide specialized services, placing patients at significant risk of harm.

29. Properly staffed operating rooms and surgeries at BDSC Hospital and Basrah Hospital is an essential component of the Contract, as these hospitals must perform surgery in accordance with U.S. standards on patients who present with varying conditions that require different levels of surgery ranging from patients requiring an emergency appendectomy to soldiers with traumatic injuries from an improvised explosive device.

30. CHS is required to provide sufficient staffing to enable two surgeries to be performed simultaneously at BDSC Hospital and one surgery at Basrah Hospital.

31. For each surgical procedure performed at BDSC Hospital and Basrah Hospital, the surgical team should be comprised of the lead surgeon and:

- A first assistant who is either a surgeon or operating room nurse depending on the length and/or complexity of the surgical procedure;
- An operating room technician to serve as the instrumentalist;
- An operating room nurse to serve as a circulator; and
- A nurse anesthetist.

32. As BDSC Hospital's operating room record log reflects, very few patients received a full surgical team for their surgery. In blatant disregard of the staffing requirements and patients' health and safety, throughout the three-year period 2013 to 2016, the first assistant was not another surgeon or properly qualified operating room nurse. Instead, CHS assigned either a nonsurgeon physician, an operating room technician, a dentist, or a medical corpsman to

serve as the first assistant. And, in several surgeries involving U.S. troops, the only individual available to be the first assistant was an untrained, non-CHS military medic.

33. To illustrate how often surgeries were understaffed, of the 107 surgical procedures performed at BDSC Hospital between January 1, 2013 and February 3, 2017, only 33 were properly staffed with a qualified first assistant – *i.e.*, a surgeon or operating room nurse. In each of the surgeries in which a qualified first assistant was not present, CHS instead scheduled an operating room technician, an emergency medical technician (EMT), a dentist, or a nonsurgeon physician.

34. To further illustrate CHS's noncompliance with operating room staffing requirements, Dr. Watkins performed 35 surgical procedures at BDSC Hospital between October 5, 2015 and September 22, 2016. He received assistance from a qualified first assistant – either a second surgeon or operating room nurse – in just seven out of those 35 surgeries. In the other 28 surgeries, an unqualified person served as Dr. Watkins's first assistant.

35. For instance, the surgical team that performed surgery on a U.S. serviceman on July 16, 2016 at BDSC Hospital to treat injuries the soldier suffered from an explosive blast merely consisted of the lead surgeon, an instrumentalist, a circulator, and a nurse anesthetist. This patient did not receive a first assistant for his surgery.

36. CHS's egregious noncompliance with its contractual and legal obligations and disregard for U.S. hospital standards is evidenced by BDSC Hospital's and Basrah Hospital's operating room staffing schedules from this period.

37. The hospital's surgeon on-call schedule for BDSC Hospital shows that over the 16-month period from October 2015 through October 2016 CHS had only one surgeon scheduled

on 193 out of the 397 days and two surgeons scheduled on 183 out of the 397 days. BDSC Hospital only had three surgeons on staff for 21 out of the 397 days.

	Days w/ 1 Surgeon (on 1st call)	Days w/ 2 Surgeons (1 on 1st call and 1 on 2nd call)	Days w/ 3 Surgeons (1 on 1st call, 1 on 2nd call, and 1 off)
Oct. 2015	28	3	0
Nov. 2015	24	3	3
Dec. 2015	0	17	14
Jan. 2016	22	5	4
Feb. 2016	21	8	0
Mar. 2016	3	28	0
Apr. 2016	1	29	0
May 2016	15	16	0
June 2016	30	0	0
July 2016	16	15	0
Aug. 2016	15	16	0
Sep. 2016	17	13	0
Oct. 2016	1	30	0
TOTAL	**193**	**183**	**21**

As a result, on half of the days during this period, a second surgeon could not serve as the first assistant, and it was impossible to perform two surgeries simultaneously at BDSC Hospital. This was a blatant violation of the Contract and Task Order.

38. BDSC Hospital's staffing schedules also show that CHS did not schedule the number of operating room nurses that the Task Order required. Likewise, the nurse on-call schedules show that for much of 2014 only one nurse anesthetist was scheduled at BDSC Hospital, not the 2.75 nurse anesthetists required by the Task Order.

39. As described above, while working as a general surgeon at BDSC Hospital from October 2015 to October 2016, Dr. Watkins witnessed and was personally impacted by the constant staffing deficiencies. Dr. Watkins repeatedly informed CHS leadership, including, but not limited to, Program Manager Morrell, Chief Medical Officer Wynn, and Director of Operations Bruce Morgan, that surgeries were being inadequately and inappropriately staffed

and that this created significant risks to the patients. CHS never addressed his concerns. As an operating room nurse, Nurse Ortega likewise witnessed and was personally impacted by the constant staffing deficiencies at BDSC Hospital.

40. CHS also placed patients who underwent surgery at Basrah Hospital at risk of harm by cutting corners on staffing. Pursuant to the Task Order, Basrah Hospital is required to be staffed with 4.25 nurses (2.00 registered nurses, 1.0 registered nurse-lead, and 1.25 operating room nurses). Yet, the nurse schedules show that for much of 2013 through 2016 Basrah Hospital was staffed with only three nurses. Additionally, there should be two registered nurses at both Condor Health Unit and Erbil Health Unit. However, in 2015 and 2016, CHS scheduled just one registered nurse to work at each of these health units.

41. The chronic understaffing at these CHS-operated hospitals negatively impacted patient care. Having someone other than a general surgeon or qualified operating room nurse serve as the first assistant extended the length of the surgeries and correspondingly the amount of time that the patients were under anesthesia. Moreover, the prolonged surgeries increased the risk of patient infection.

42. For example, an appendectomy performed on a military contractor on November 5, 2015 took significantly longer than it should have because two unqualified military medical corpsmen filled in as the first assistant on the surgery.

43. In addition, each surgeon had an excessive patient load, resulting in fatigue which in turn increased the risk of errors.

44. Had DoS been aware that unqualified and untrained persons were performing critical technical functions during surgeries and that CHS exposed patients to an increased risk of harm, it would not have paid CHS for these surgical services.

2. Unqualified pharmacy technicians and nurse anesthetists often ran the pharmacies at BDSC Hospital and Basrah Hospital, leading to frequent medication errors.

45. The pharmacy at BDSC Hospital is required to always be staffed with one pharmacist and one pharmacy technician. (*See* Task Order at 56). The pharmacy at Basrah Hospital is required to always be staffed by one pharmacy technician who is supposed to be supervised remotely by the pharmacist at BDSC Hospital. (*See id.* at 55).

46. State laws governing pharmacy operations require that pharmacies be directly supervised by a licensed pharmacist. (*See, e.g.*, Fla. Stat. §§ 465.001 *et seq.*). The pharmacist is responsible for all dispensing decisions and is liable for any negligence or errors.

47. A pharmacy technician can assist a pharmacist with filling prescriptions (such as by counting out and bottling pills) and stocking drugs. A pharmacist must supervise the pharmacy technician, direct all of the technical tasks, and determine those functions that the pharmacy technician is capable of performing. Pharmacy technicians lack the education and expertise to perform other critical roles of pharmacists, including compounding medications, recognizing potentially adverse drug reactions, and identifying possible drug abuse or diversion.[8]

48. U.S. contractors typically comply with federal and state law in dispensing prescription medication and controlled substances.

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[8] When a patient gets a prescription filled at a pharmacy, he or she relies on the pharmacist to have placed the right medication in the container, included medication of the correct dosage, and provided the proper directions about how to take the medication. If these things do not happen, the consequences could be tragic. Similarly, the label on a bottle, container, or vial of medication serves a critical purpose, letting the patient or provider know what the medication is, the dose of the drug, the timing of taking the medication, and any drug interactions that might be harmful to the patient. The labels enable the patient to take the medication or the provider to deliver the medication in the correct manner. However, if something is mislabeled, the consequences can include the patient taking the wrong medication, overdose, underdose, poisoning, or death.

49. In violation of the Contract and federal and state law, CHS often staffed the pharmacy at BDSC Hospital with only a pharmacy technician and without a pharmacist on-site to supervise the technician. And because the pharmacist at BDSC Hospital remotely supervises the pharmacy technician at Basrah Hospital, any time there was not a pharmacist working at BDSC Hospital, the pharmacy technician at Basrah Hospital was likewise unsupervised. CHS also often had nurse anesthetists serve as pharmacists without any supervision. Accordingly, the unsupervised pharmacy technicians and nurse anesthetists managed the pharmacies, filled prescriptions, and dispensed controlled substances and prescription drugs.[9]

50. The unsupervised nurse anesthetists and pharmacy technicians dispensed medications at the BDSC Hospital and Basrah Hospital without appropriately considering possible side effects or contraindications and frequently without providing proper instructions for use. Furthermore, inadequate staffing led to substandard drug inventory practices and the failure to dispose of expired drugs. As a result, the unsupervised nurse anesthetists and pharmacy technicians dispensed to unsuspecting patients expired drugs that may have lost some of their potency and effectiveness.

51. By having unqualified individuals serve as pharmacists, CHS demonstrated its complete disregard for patients' health and safety. The men and women who received medicines from the BDSC Hospital and Basrah Hospital, deserved better treatment; the U.S. paid CHS to provide better treatment.

52. The dangers of having unqualified individuals serve as pharmacists were manifested by the errors committed by the pharmacy technicians and nurse anesthetists at the

[9] It should also be noted that certain physicians at BDSC Hospital were prescribing controlled substances even though they did not have an active DEA registration.

BDSC Hospital pharmacy. For example, a U.S. serviceman's health and safety was placed at risk in January 2016 when an unsupervised pharmacy technician compounded and dispensed with incorrect instructions acetylcysteine 20% (a drug commonly used by emergency rooms to treat patients who have received an overdose of acetaminophen). Although the intravenous form of acetylcysteine had been prescribed, the pharmacy only had the formulation that could be taken orally or inhaled. Rather than consulting with a pharmacist or the prescribing physician, the pharmacy technician compounded the oral/inhaled formulation of acetylcysteine 20% so that it could be administered intravenously. The patient received all of the compounded doses by IV. Dr. Smith reported this incident to CHS in a memorandum dated April 26, 2016. CHS did not address the pharmacy staffing issues after receiving Dr. Smith's memorandum.

53. In another example of a dispensing error by an unsupervised "pharmacy custodian," in October 2016, a pharmacy custodian at BDSC Hospital erroneously dispensed OxyNorm 5 mg capsules (oxycodone hydrochloride) to a patient who had received a prescription for Percocet (oxycodone and acetaminophen). The OxyNorm was provided to the patient in a ziploc bag with the prescription for Percocet taped to it.

54. The nurse anesthetists and pharmacy technicians risked being fired by CHS if they refused to serve as a pharmacist. For instance, in early 2016, CHS terminated a nurse anesthetist who refused to cover as the pharmacist at Basrah Hospital because he felt it was beyond the scope of his practice and expertise and would violate state law.

55. In April 2015, Dr. Smith sent an email to Program Support Manager Laurie Tufts, who works at CHS's headquarters in the U.S., to express his concerns about CHS's dangerous practice of allowing unqualified personnel to act as pharmacists. CHS failed to address the problems and instead stated that the technicians and nurse anesthetists could be supervised by

nurse practitioners, physician assistants, and/or physicians. However, the nurse practitioners, physician assistants, and physicians themselves were also not qualified to supervise pharmacy operations and did not engage in meaningful supervision. Consequently, to avoid having unqualified personnel dispense drugs in his absence, Dr. Smith worked without a day off for approximately five months (January 29, 2016 to June 27, 2016).

56. In an apparent attempt to conceal that it was having unsupervised and unqualified pharmacy technicians and nurse anesthetists perform the functions of a pharmacist, CHS referred to these staff members as "pharmacy custodians." In its internal procedures, CHS defines the "pharmacy custodian" as "[a] person responsible for securing and managing the controlled medications that are received, stored and issued from the pharmacy in accordance with sound pharmacy procedures." (CHS's MSSI Controlled Substances Procedures at 6).

57. If CHS had disclosed to DoS that unsupervised pharmacy technicians and nurse anesthetists were serving as pharmacists at BDSC Hospital and Basrah Hospital, DoS would not have paid CHS for such pharmacy services.[10]

3. Radiology technicians lacking expertise in computed tomography performed CT scans using equipment that was not properly maintained.

58. A computed tomography (CT) scan is a procedure that uses specialized X-ray equipment to produce cross-sectional images of the body, which are used for a variety of diagnostic and therapeutic purposes. Because the patient is exposed to high doses of ionizing radiation, even when performed properly, there are risks associated with a CT scan, such as

[10] CHS's disregard for pharmacy standards and requirements similarly led to dispensing errors and unaccounted for drugs at the pharmacy at another CHS-operated medical facility in Balad, Iraq. Indeed, Dr. Smith believes that improper management of this pharmacy led to use of an expired and improperly stored anesthesia drug Diprivan (propofol) that was a contributing factor to an overdose death.

increasing a person's lifetime risk of developing cancer or a possible reaction to the intravenous contrast agent or dye that may be used to improve visualization.

59. If CT equipment is not properly maintained and calibrated, the patient could receive an excessive, perhaps even toxic, dose of radiation, or the quality of the CT image could be impacted, leading to a false positive or false negative.

60. To mitigate these risks, medical facilities that perform CT scans typically have an imaging team consisting of a radiologist, radiology technician/technologist, radiation physicist, and radiation safety officer (RSO) that establish quality control and patient safety protocols to ensure that the radiation technician/technologist administers the lowest radiation dose that will yield an image quality adequate for diagnosis and intervention.

61. To be accredited by the American College of Radiology, a facility that performs CT scans must maintain a documented quality control program and must conduct the following quality control testing of the CT equipment at the stated frequency to ensure that the CT equipment performs in a consistent manner and yields acceptable images:

TEST	OBJECTIVE
DAILY TESTS TO BE PERFORMED BY A RADIOLOGIC TECHNOLOGIST/TECHNICIAN:	
Water CT Number & Standard Deviation	To ensure that the relative calibration of all CT numbers to water remains within acceptable limits and that quantum noise and electronic system noise do not increase. Too much image noise degrades low-contrast detectability.
Artifact Evaluation	To identify and correct artifacts in images of a uniform test phantom before they become severe enough to be detected in patient images.
WEEKLY TESTS TO BE PERFORMED BY A RADIOLOGIC TECHNOLOGIST/TECHNICIAN:	
Wet Laser Printer Quality Control	To ensure artifact-free images printed on film are produced with consistent gray levels that match the image appearance on the filming console.
MONTHLY TESTS TO BE PERFORMED BY A RADIOLOGIC TECHNOLOGIST/TECHNICIAN:	
Visual Checklist	To ensure the CT system's patient bed transport, alignment and system indicator lights, intercom, the emergency cart, room safety lights, signage, and monitors are present, working properly, and are mechanically and electrically stable.
Dry Laser Printer Quality Control	To ensure that all images printed on film are of diagnostic quality—to be used for interpretation, if necessary—and that they are artifact-free, produced with consistent gray levels, and match the image appearance on the filming console.
Display Monitor Quality Control	To ensure that images on the monitors of the CT scanner display the entire range of gray shades produced by the CT scanner.
ANNUAL TESTS TO BE CONDUCTED BY A MEDICAL PHYSICIST:	
Review of Clinical Protocols	• To ensure that a selection of clinical protocols appropriately utilizes the scanner features, including kV, mAs, detector configuration, reconstructed scan width, pitch, reconstruction algorithm, and other features such as dose reduction options, including automatic exposure controls, iterative reconstruction techniques, etc. • To ensure that these protocols obtain the diagnostic image quality required for the CT exam while minimizing radiation dose to the patient.
Scout Prescription and Alignment Light Accuracy	To verify that the incorporated alignment lights correctly indicate the scan position and that the scout image prescription correctly identifies the scan position.
Image Thickness	To verify that the reconstructed image thickness agrees with the nominal value.
Table Travel Accuracy	To verify that the patient table translates as indicated.
Radiation Beam Width	To measure the radiation beam width and to assess its relationship to the nominal collimated beam width.
Low-Contrast Performance	To verify that the low-contrast performance of clinical protocols is adequate for diagnosis.
Spatial Resolution	To verify that the spatial resolution performance of clinical protocols is adequate for diagnosis.
CT Number Accuracy	To verify that the CT numbers reported by the CT scanner are acceptably accurate and vary as expected.
Artifact Evaluation	To identify and correct artifacts in images of a uniform test phantom before they become severe enough to be detected in patient images.
CT Number Uniformity	To identify and correct nonuniformities in the CT numbers in images of a uniform test phantom before they become severe enough to impact patient diagnosis.
Dosimetry	To measure doses for verification of scanner performance and to allow for calculation of dosimetric quantities relevant to patient exam estimates.
Gray Level Performance of CT Acquisition Display Monitors	To ensure that images on the CT scanner monitors display the entire range of gray shades produced by the CT scanner.

(American College of Radiology Computed Tomography Quality Control Manual (2012)).

62. In accordance with the Task Order, BDSC Hospital and Basrah Hospital both have a CT scanner and have radiology technicians on staff to perform CT scans. The hospitals perform one to three CT scans per day.

63. CHS did not have a system in place at the hospitals to ensure that quality control tests of the CT equipment were performed and that radiation dose levels and radiation exposure (by patients and staff) were monitored. It also provided no training to radiology technicians about proper testing and maintenance of the CT equipment.

64. In addition, CHS did not have a radiologist on site. Nor did it have a radiation physicist or RSO on staff at BDSC Hospital or Basrah Hospital. Instead, CHS merely staffed the hospitals with radiology technicians. To make matters worse, some of the radiology technicians at Basrah Hospital lacked adequate training to perform CT scans.

65. In fact, since CHS does not have an appropriate quality control and equipment testing protocol, some of the radiology technicians who became concerned about patient safety and image quality educated themselves about quality control tests. Additionally, at least one radiology technician repeatedly asked CHS to pay for her to receive RSO training during her free time. CHS, which showed no interest in quality control, rejected the requests.

66. Although radiology technicians are supposed to record the level of the dose of radiation given to patients, many of the radiology technicians assigned to BDSC Hospital and Basrah Hospital were not even trained on how to measure and monitor the dose of radiation provided to the patients, a process called dosimetry. And because CHS did not have a radiologist

on site and did not have a radiation physicist or RSO, no one has been monitoring the radiation doses that patients at BDSC Hospital and Basrah Hospital have received.[11]

67. As a result of CHS's failure to ensure that all radiology technicians were properly trained to perform CT scans and its failure to establish and apply appropriate quality control protocols, Relators believe that numerous patients may have received an excessive level of radiation and that many patients' CT image was adversely impacted, which could have led to false negatives or false positives.

68. Moreover, because CHS did not perform proper maintenance and quality control testing on the CT equipment, on a few occasions patients who needed an emergency CT scan could not receive one. For example, when several marines who arrived at BDSC Hospital in March 2016 with injuries from rockets launched by ISIS militants, they could not receive needed CT scans because the CT equipment malfunctioned.[12]

69. If CHS had disclosed to DoS that it staffed the CT scanner with unqualified radiology technicians, did not properly monitor radiation doses, and did not properly maintain and test the CT equipment, DoS would have refused to pay for the CT services CHS provided.

VI. COUNTS

COUNT I
Violations of 31 U.S.C. § 3729(a)(1)(A)

70. Relators hereby incorporate and re-allege paragraphs 1 through 69 as though fully set forth herein.

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[11] Although CHS employs a RSO in the U.S., it did not have the RSO inspect the CT equipment at BDSC Hospital and Basrah Hospital.

[12] It should be noted that the Internet network at BDSC Hospital was unreliable, often slowing the transfer of CT images to the radiologists in the U.S. for review. This delayed treatment decisions on multiple occasions.

71. CHS, by and through its agents, officers, and employees, violated 31 U.S.C. § 3729(a)(1)(A) by knowingly presenting, or causing to be presented, to DoS false claims for payment under the Contract for services provided under that agreement. CHS and its agents, officers, and employees falsely certified in the claims for payment that the services CHS provided satisfied all of the requirements and standards of the Contract, the Task Orders issued thereunder, federal and state law, and U.S. standards, regarding, among other things:

(a) the licensing and qualifications of all personnel, including doctors, nurses, pharmacists, and radiology technicians;

(b) the staffing of the operating rooms, pharmacies, and radiology centers at BDSC Hospital and Basrah Hospital;

(c) the dispensing practices for controlled substances and prescription drugs at the pharmacies at BDSC Hospital and Basrah Hospital; and

(d) proper maintenance of the CT equipment at BDSC Hospital and Basrah Hospital.

For the reasons described above, the services provided by CHS under the Contract were not consistent with the requirements of the Contract, the Task Orders, federal and state law, and U.S. standards.

72. CHS's certifications were material to DoS's decisions to pay CHS for its services. If CHS had informed DoS that it was having unqualified and untrained individuals perform critical functions and that the services it provided were drastically below U.S. standards, DoS would not have paid CHS for the services.

73. In engaging in the conduct alleged above, CHS acted "knowingly" as that term is defined in 31 U.S.C. § 3729, in that it acted with actual knowledge, deliberate ignorance, or reckless disregard of the truth or falsity of the information.

74. As a result of CHS's violations of 31 U.S.C. § 3729(a)(1)(A), the United States has suffered damages in an amount to be determined at trial.

COUNT II
Violations of 31 U.S.C. § 3729(a)(1)(B)

75. Relators hereby incorporate and re-allege paragraphs 1 through 69 as though fully set forth herein.

76. CHS, by and through its agents, officers, and employees, in violation of 31 U.S.C. § 3729(a)(1)(B), knowingly made, used, or caused to be made or used, false records or statements material to claims for reimbursement for services provided under the Contract that were paid by DoS. These false records and statements included false certifications and records stating or implying that the services CHS provided satisfied all of the requirements and standards of the Contract, the Task Orders issued thereunder, federal and state law, and U.S. standards, regarding, among other things:

(a) the licensing and qualifications of all personnel, including doctors, nurses, pharmacists, and radiology technicians;

(b) the staffing of the operating rooms, pharmacies, and radiology centers at BDSC Hospital and Basrah Hospital;

(c) the dispensing practices for controlled substances and prescription drugs at the pharmacies at BDSC Hospital and Basrah Hospital; and

(d) proper maintenance of the CT equipment at BDSC Hospital and Basrah Hospital.

For the reasons described above, the services provided by CHS under the Contract were not consistent with the requirements of the Contract, the Task Orders, federal and state law, and U.S. standards.

77. CHS's certifications and statements were material to DoS's decisions to pay CHS for its services. If CHS had informed DoS that it was having unqualified and untrained individuals perform critical functions and that the services it provided were drastically below U.S. standards, DoS would not have paid CHS for the services.

78. In engaging in the conduct alleged above, CHS acted "knowingly" as that term is defined in 31 U.S.C. § 3729, in that it acted with actual knowledge, deliberate ignorance, or reckless disregard of the truth or falsity of the information.

79. As a result of CHS's violations of 31 U.S.C. § 3729(a)(1)(B), the United States has suffered damages in an amount to be determined at trial.

VII. PRAYER FOR RELIEF

WHEREFORE, Relators demand that judgment be entered in favor of the United States and against CHS for the maximum amount of damages and such other relief as the Court may deem appropriate on each Count. This includes three times the amount of damages to the United States plus civil penalties of no more than $11,000 and no less than $5,500 for each false claim before or on November 2, 2015, and civil penalties of no more than $21,916 and no less than $10,957 for each violation after November 2, 2015, and any other recoveries or relief provided for under the FCA. Further, Relators request that they receive the maximum amount permitted by law from the proceeds or settlement of this action as well as from any alternative remedies collected by the United States, plus reasonable expenses necessarily incurred, and reasonable attorneys' fees and costs. Relators request that their award be based upon the total value recovered, both tangible and intangible, including any amounts received from individuals or entities who are not parties to this action.

VIII. DEMAND FOR JURY TRIAL

A jury trial is demanded in this case.

DATED: July 19, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I will cause a copy of the above Complaint to be served upon the following counsel by certified mail, return receipt requested:

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DATED: July 19, 2017